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SECTION10.0 SUMMARY OF SAFETY AND EFFECTIVENESS

510(K) SUMMARY	
10.1	**ADMINISTRATION INFORMATION**
10.11	**SPONSOR IDENTIFICATION** JiangSu YuYue Medical Equipment & Supply Co., Ltd. Zhenxin Road, Yunyang Economical Development Zone, Danyang City, Jiangsu Province, CHINA, 212300. **Contact Person**: Mr. James Lin **Tel**: (86511)86900991 **Fax**:(86511)86900991 email: james.lin@yuyue.com.cn
10.12	**ESTABLISHMENT REGISTRATION NUMBER:** Pending
10.13	**OFFICIAL CONTACT PERSON** Mr. Jiuguang Song Managing Director Strategic Advatage Consulting.Inc. Jiuguang Song Managing Director STRATEGIC ADVANTAGE CONSULTING.INC 3119 Brick Lane,Decatur.GA30033 Tel: 404-294-0743 Fax:831-300-3572 songjiuguang@yahoo.com
10.14	**DATE OF PREPARATION OF THIS SUMMARY:** August 10, 2011
10.15	**PROPRIETARY (TRADE) NAME:** YUYUE K2 wheelchair、YUYUE K4 wheelchair
10.16	**COMMON NAME:** Wheelchair
10.17	**CLASSIFICATION NAME:** Wheelchair, Mechanical
10.18	**REGULATION NUMBER:** 21 CFR 890.3850
10.19	**PROPOSED REGULATORY CLASS:** Class I
10.20	**MEDICAL SPECIFICATIONS:** Physical medicine
10.21	**DEVICE PRODUCT CODES:** 89 IOR
10.3	**DESCRIPTION OF DEVICE:** The YUYUE K2/K4 wheelchair is a wheelchair that provides mobility to

	persons limited to a sitting position. It consists of rigid, mechanical, steel frame and nylon upholstery back and seat that meet ISO 7176-16: Resistance to ignition of Upholstered parts. It has two 24 " rear wheels and two 8" front casters for turning and maneuverability. The YUYUE K2/K4 wheelchair is intended for the use in indoors and outdoors, over smooth surface (all standard indoor flooring surfaces, concrete, asphalt and pocked dirt) that free of large obstacles and inclines greater than 9 degrees.
10.4	**INDICATION FOR USE** The YUYUE K2/K4 wheelchair is indicated for providing mobility to persons limited to a sitting position.
10.5	**COMPARISON OF TECHNICAL CHARACTERISTICS** YUYUE K2/K4 wheelchair and Danyang Huayi K2 wheelchair (K080207) have the same technological characteristics.
10.6	**TECHNICAL CHARACTERISTICS SUMMARY** YUYUE K2/K4 wheelchair production meets the following standards: • ISO 7176-1 Wheelchair: Determination of static stability • ISO 7176-3 Wheelchair: Determination of efficiency of brakes. • ISO 7176-5: Determination of overall dimension, mass and turning space. • ISO 7176-7: Measurement of seating and wheel dimensions. • ISO 7176-8 Wheelchair: Requirements and test methods for static, impact and fatigue strengths. • ISO 7176-15 Wheelchair: Requirements for information disclosure, documentation and labeling. • ISO 7176-16 Wheelchair: Resistance to ignition of upholstered parts – requirements and test methods. • ISO 10993-5-2009: Biological Evaluation of Medical Devices – Part5: Testes for in vitro Cytotoxicity • ASTM D751:2006 Section 11-Procedure A- Tensile Strength • Section A, Part I and Section D, Part II of California Technical Bulletin 117 Requirement: Test Procedure and Apparatus for Testing the Flame Retardance of Resilient Filling Materials Used in Upholstered Furniture. • PVC leather/Nylon fabric/liner in accordance with: Section E, Part I of California Technical Bulletin 117 Requirement: Test Procedure and Apparatus for Testing the Flame Retardance of Resilient Filling Materials Used in Upholstered Furniture.
10.7	**PREDICATE DEVICE:** Danyang Huayi K2 wheelchair (K080207)

10.8	**SUBSTANTIAL EQUIVALENCE:** In the domestic market sales, YUYUE K2/K4 wheelchair has good quality and stability. Market information feedback to the product quality and reliable. YUYUE K2/K4 wheelchair and Danyang Huayi K2 wheelchair (K080207) have the same structure and effective consistent performance, and customers responded well. YUYUE K2/K4 wheelchair and Danyang Huayi K2 wheelchair (K080207) are substantially equivalent products in all areas impacting safety and effectiveness.
10.9	**CONCLUSION:** YUYUE K2/K4 wheelchair confirm fully to the standards which are mentioned in Section as well as applicable 21 CFR references, and meet pinhole FDA requirements, biocompatibility requirements and labeling claims required by these standards. There are no safety/efficiency issues or claims that differ from the predicate devices cited.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JiangSu YuYue Medical Equipment & Supply Co., Ltd.
% Underwriters Laboratories Inc.
Mr. Ned Devine
333 Pfingsten Road
Northbrook, Illinois 60062

MAR 26 2012

Re: K120526
Trade/Device Name: YUYUE K2/K4 wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: February 14, 2012
Received: February 22, 2012

Dear Mr. Devine:

This letter corrects our substantially equivalent letter of March 8, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

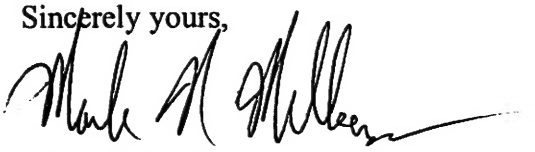
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4.0 INDICATIONS FOR USE

Indications for Use

510(k) Number (if known):

Device Name: YUYUE K2/K4 wheelchair

Indications For Use:

The YUYUE K2/K4 wheelchair is indicated for providing mobility to persons limited to a sitting position.

Prescription Use __Yes__ **AND/OR Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120526